IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Art Unit: 1805
CLASSEN, J. Barthelow	)	Examiner: VOGEL, N.
Serial No.: 08/104,529	)	Washington, D.C.
Filed: August 12, 1993	)	November 6, 1995
For: METHOD AND COMPOSITION FOR AN EARLY VACCINE...	)	Docket No.: CLASSEN=1

SECOND SUPPLEMENTAL RESPONSE

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

S i r :

Applicants are still awaiting action on the Amendment filed April 10, 1995 and the Supplemental Amendment filed April 12, 1995.

Applicants wish to call to the Examiner's attention the Final Utility Examination Guidelines, which became effective on July 15, 1995. These Guidelines state that when the enablement issue raised under 35 U.S.C. §112 is based on lack of utility/inoperability, the standard applied is the same one set forth under §101, i.e., whether the asserted utility would be more likely than not to be considered credible by a person of ordinary skill in the art. The Guidelines indicate that "data from in vitro or animal testing is generally sufficient to support therapeutic utility." Applicants' evidence of operability, as set forth in the specification and in

literature exhibits, plainly supports the instant claims, when judged under these Guidelines. Indeed, Applicants believe that under the Guidelines, the limitation of the claims to diabetes was unnecessary.

Respectfully submitted,

BROWDY AND NEIMARK
Attorneys for Applicant

By: _____
Iver P. Cooper
Reg. No. 28,005

419 Seventh Street, N.W.
Washington, D.C. 20004
Telephone: (202) 628-5197
Facsimile: (202) 737-3528
IPC:lms

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